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Docket No. SYN-064 C

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MAIL STOP: APPEAL BRIEF-PATENTS

By: Gregory L. Mayback (40,719)

Date: June 6, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Before the Board of Patent Appeals and Interferences

Applic. No. : 10/010,246 Confirmation No.: 5866  
Applicant : Robert Sixto Jr., et al.  
Filed : December 6, 2001  
Title : Surgical Clips Particularly Useful in the  
Endoluminal Treatment of Gastroesophageal  
Reflux Disease (GERD)  
Group Art Unit : 3731  
Examiner : Bradford C. Pantuck  
Docket No. : SYN-064 C  
Customer No. : 44338

Hon. Commissioner for Patents  
Alexandria, VA 22313-1450

BRIEF ON APPEAL

S i r :

This is an appeal from the final rejection in the Office  
action dated January 5, 2005, finally rejecting claims 1-10,  
17, 18, and 21-31.

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Appellants submit this *Brief on Appeal* in triplicate,  
including payment in the amount of \$500.00 to cover the fee  
for filing the *Brief on Appeal*.

Real Party in Interest:

This application is assigned to Inscope Development, LLC of Miami, Florida. The assignment was recorded on March 20, 2003 under Reel/Frame 013495/0344.

Related Appeals and Interferences:

No related appeals or interference proceedings are currently pending which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims:

Claims 1-10, 17, 18, and 21-31 are rejected and are under appeal. Claims 11-16, 19, and 20 were cancelled.

Status of Amendments:

No claims were amended after the final Office action. A Response under 37 CFR § 1.116 was filed together with a Notice of Appeal on March 7, 2005. The Primary Examiner stated in an Advisory Action dated April 5, 2005 that the request for reconsideration had been considered but did not place the application in condition for allowance.

Summary of the Claimed Subject Matter:

As stated in the second paragraph on page 2 of the specification of the instant application, the invention relates to endoscopic surgical procedures and instruments. More particularly, the invention relates to surgical clips which are particularly useful in the transoral invagination and fundoplication of the stomach to the esophagus.

Appellants explained on page 15 of the specification, line 3, that, referring to the figures of the drawings in detail and first, particularly to Fig. 1 thereof, there is shown a clip applier 10 according to the invention generally include a flexible wound outer coil 12 having a proximal end 14 and a distal end 16. An end effector assembly 18 is coupled to the distal end 16 of the coil 12 and an actuator assembly 20 is coupled to the proximal end 14 of the coil 12. A plurality of pull/push wires 58, 60 (shown and described below with reference to Figures 2-4) extend through the coil 12 and couple the end effector assembly 18 to the actuator assembly 20. The clip applier 10 is similar to the clip applier described in detail in previously incorporated co-owned application Serial Number 10/010,900, entitled "Flexible Surgical Clip Applier". However, in this application, the end effector assembly 18 is designed specifically for fundoplication using a clip significantly larger than that

used in the clip applier of the aforesaid co-owned application.

On page 15 of the specification, line 19, Appellants outlined that Figures 2-4 illustrate the details of the end effector assembly 18 according to a first embodiment of the invention. The end effector assembly 18 includes a pair of jaws 22, 24 which are rotatably coupled to a clevis 26. In particular, the clevis 26 has a central channel 28 (seen best in Figure 4) which is defined by clevis arms 30, 32. Although the term "clevis" is used because of its general acceptance in the art of endoscopic instruments, the "clevis" 26 is preferably covered on top and bottom so that the only exit from the channel 28 is at the distal end. The jaw 22 is rotatably coupled to the clevis arm 30 by an axle 34 and the jaw 24 is rotatably coupled to the clevis arm 32 by an axle 36. The axles 34 and 36 are dimensioned such that they do not significantly obscure the channel 28.

It is further stated on page 16 of the specification, line 8, that the jaws 22, 24 are substantially identical. Each jaw 22, 24 includes a proximal tang 38, 40, a mounting bore 42, 44, a distal hook shaped anvil 46, 48 and a plurality of medial teeth 50, 52. As seen best in Figure 4, the medial teeth 50, 52 are arranged on one side of the jaw and a short

wall 51, 53 is arranged on the opposite side of the jaw to define a groove (or guiding channel) 54, 56. The grooves 54, 56 meet the anvils 46, 48 each of which has a helical surface. The interior (proximal) helical surfaces of the anvils act to bend the clip retainers as described below with reference to Figures 19-24.

It is described in the last paragraph on page 16 of the specification, line 19, that the proximal tang 38, 40 of each jaw is coupled to a respective pull/push wire 58, 60 via two links 62, 64 and 66, 68. The links 62, 66 are substantially L-shaped and are rotatably coupled near their elbow to the clevis arms 30, 32 by axles 70, 72 which do not significantly obscure the channel 28 between the clevis arms. One end of the link 62, 66 is coupled to the pull/push wire 58, 60 and the other end of the link 62, 66 is rotatably coupled to one end of the link 64, 68. The other end of the link 64, 68 is rotatably coupled to the tang 38, 40. The combined coupling of each jaw 22, 24 to each pull/push wire 58, 60 forms a linkage which amplifies the force from the pull/push wires to the jaws. In particular, as the jaws close, the mechanical advantage increases.

However, appellants outlined on page 17 of the specification, line 8, that the proximal ends of the pull/push wires 58, 60

are coupled to the actuator assembly (20 in Figure 1) as described in previously incorporated co-owned application Serial Number 10/010,900, entitled "Flexible Surgical Clip Applier".

As set forth in the last paragraph on page 17, a clip pusher (not shown) disposed in the interior of the coil is coupled to a push wire (not shown) which is coupled to the actuator assembly as described in previously incorporated co-owned application Serial Number 10/010,900, entitled "Flexible Surgical Clip Applier". Unlike the previously incorporated co-owned application, the jaws of the instant clip applier are significantly longer and designed for use with clips approximately 17-20mm long (after the clip is applied) as compared to the 5-7mm clips shown in the previously incorporated co-owned application.

Appellants explained on page 18 of the specification, line 1, that, turning now to Figures 5-8, a second embodiment of the jaws 22', 24' is illustrated. The jaws 22', 24' are substantially identical to each other and are designed for use with any of the clips illustrated in Figures 19-24. Each jaw 22', 24' includes a proximal tang 38', 40', a mounting bore 42', 44', a distal hook shaped anvil 46', 48' and a plurality of medial teeth 50', 52'. The medial teeth 50', 52' are

arranged on one side of the jaw and a short wall 51', 53' is arranged on the opposite side of the jaw to define a groove (or guiding channel) 54', 56'. The grooves 54', 56' meet the interior surfaces of the anvils 46', 48' which curve about a single axis. The interior surfaces of the anvils act to bend the clip retainers as described below with reference to Figures 19-24 and as shown by the clip 310 in Figure 5. According to this embodiment, as seen best in Figures 6-8, the guiding channels 54', 56' and the anvils 46', 48' are angled relative to the vertical axis of the jaw 22', 24'. This angle causes the clip to twist as it is pushed through the jaws so that the ends of the clip are offset as shown in Figure 5, for example. According to the presently preferred embodiment, the guiding channels 54', 56' and the anvils 46', 48' are angled approximately 22° relative to the vertical axis of the jaw 22', 24'. According to a method of the invention, clips for use with this embodiment of the jaws are prebent in the bridge area to facilitate movement through the angled channels.

It is further stated on page 19 of the specification, line 1, that, in Figure 9, a third embodiment of the jaws 22", 24" is illustrated. The jaws 22", 24" are not identical to each other and are designed for use with clips of the type illustrated in Figures 17-18. Each jaw 22", 24" includes a proximal tang 38", 40" and a mounting bore 42", 44". One jaw



22" terminates with two spaced apart distal hooks 46", 47" and has two rows of medial teeth 50". The other jaw 24" terminates with a single distal hook shaped anvil 48" and has two rows of medial teeth 52". The medial teeth 50", 52" are arranged on both sides of the jaw and a groove (or guiding channel) 54", 56" lies between the rows of teeth. The groove 54" terminates with an undercut well (not shown), as described in co-owned Serial Number --/---,--, whereas the groove 56" continues on to the interior of the anvil 48" which has a surface which curves about a single axis. Those skilled in the art will appreciate that when the jaws are closed, the anvil 48" will reside between the hooks 46" and 47" and the teeth 50" will be interleaved with the teeth 52". The interior surface of the anvil 48" bends the clip retainer as described below with reference to Figures 17-18 and as shown and described in previously incorporated co-owned applications Serial Number 09/891,775, and Serial Number --/---,---.

Appellants outlined on page 19 of the specification, line 23, that, turning now to Figures 10-14, a method of using the clip applier of the invention is illustrated in context with an existing endoscope 100 having a single lumen through which a small grasper 102 is supplied and an external working channel 104 which is attached to the scope 100 and through which the clip applier is delivered. The external working channel 104

is preferably one of the type described in previously incorporated application Serial Number 09/931,528, filed August 16, 2001, entitled "Methods and Apparatus for Delivering a Medical Instrument Over an Endoscope while the Endoscope is in a Body Lumen".

Appellants also outlined on page 20 of the specification, line 9, that, according to a method of the invention, after the endoscope assembly is delivered transorally to the procedural site, as shown in Figure 10, the fundus is grasped by the graspers and pulled in between the open jaws of the clip applier. The jaws of the clip applier are then closed onto the invaginated fundus as shown in Figure 11. As the jaws are closed the medial teeth of the jaws puncture the invaginated fundus as shown in Figures 11 and 12. When the jaws are completely closed (or closed as much as possible), they are preferably locked, the grasper is optionally released, and the clip pusher is activated to push forward a clip 106 as shown in Figure 12 and as described in the previously incorporated, co-owned, simultaneously filed application and discussed in detail hereinafter.

Appellants stated in the last paragraph of the specification, page 20, that, after the clip 106 is applied, the jaws of the clip applier are opened as shown in Figure 13 and the clip 106

remains in place and plicates the fundus. Depending on the location of the clip and the nature of the patient's condition, a single clip may be sufficient. If other clips are deemed desirable by the practitioner, the clip applier is removed and re-loaded with another clip. After re-delivering the clip applier, the procedure may be repeated at another location as shown in Figure 14. Given the size of the clips of the invention, anywhere from 1-4 clips will typically be used.

As stated on page 21, line 9, according to one aspect of the invention, the medial teeth on the jaws of the clip applier are long enough and sharp enough to damage the fundus sufficiently such that when the fundus heals adhesion occurs, binding the plicated fundus to the extent that the clip may no longer be needed. Thus, preferably, the teeth are long enough to pierce all layers of the fundus.

It is outlined on page 21, line 16, that, from the foregoing, those skilled in the art will appreciate that the methods of the invention may be performed with different types of graspers. In particular, alternative grasping devices such as a "cork screw" grasper can be used in conjunction with the clip applier of the invention to perform the methods of the invention.

As set forth in the last paragraph on page 21, it will also be appreciated that the clip applier of the invention may be attached to an endoscope in other ways as described in previously incorporated application Serial Number 09/931,528, filed August 16, 2001, entitled "Methods and Apparatus for Delivering a Medical Instrument Over an Endoscope while the Endoscope is in a Body Lumen".

Appellants explained on page 22 of the specification, line 5, that, as mentioned above, the clip applier of the invention has an outside diameter of approximately 6mm. As shown in Figures 10-14, the clip applier is used in conjunction with an endoscope having an outside diameter of approximately 12mm. To accommodate the clip applier, an exterior working channel having an exterior diameter of approximately 7mm is optionally coupled to the endoscope as described in the previously incorporated co-owned applications Serial Numbers 09/931,528 and 60/292,419.

Appellants further explained on page 22, line 14, that, Figure 15 is a scale representation of the cross-sectional area of the 12mm endoscope 100 with the attached external 7mm working channel 104, shown in horizontal shading. The cross sectional area of a prior art device 108 having an exterior diameter of

approximately 24mm is shown in diagonal shading. From Figure 15, it will be appreciated that the methods and apparatus of the invention allow for a substantially smaller device which is more easily delivered transorally and which is more easily manipulated. The overall cross-sectional area of the apparatus of the invention is approximately 152 mm<sup>2</sup> as compared to the 314mm<sup>2</sup> of the prior art devices.

It is described on page 23, line 1, that, as mentioned, the clip applier of the invention may also be used with a dual lumen endoscope. Figure 16 is a scale representation of a dual lumen endoscope 110 having an optical lumen 112 and two 6mm working lumina 114, 116. As compared to the device 108 in Figure 15, the endoscope 110 has a substantially smaller cross-sectional area than the prior art device.

Appellants also describe on page 23, line 8, that the clips used by the clip applier of the invention are substantially longer than the clips described in the previously incorporated co-owned applications, Serial Number 09/891,775 and the simultaneously filed application, which are approximately 7mm in length and adequate for general surgical applications. The retainer portion of the clips of the present invention are substantially longer in order to assure that all of the layers of the fundus are punctured.

It is outlined in the last paragraph of page 23, that, turning now to Figures 17 and 18, a first embodiment of a surgical clip 210 according to the invention includes first and second arms 212, 214, respectively, and a bridge portion 216 therebetween such that the arms and bridge portion are in a generally U-shaped configuration. The first arm 12 is provided with an end catch 220, and the second arm 214 extends (or transitions) into a deformable retainer 222 having a tissue piercing tip 224 and a plurality of catch engagements, e.g. 226, 228. The arms define an open space 230 between them. The clip 210 is preferably made from a unitary piece of titanium, titanium alloy, stainless steel, tantalum, platinum, other high Z (substantially radiopaque) materials, nickel-titanium alloy, martensitic alloy, or plastic, although other suitable biocompatible materials may be used. The first and second arms 212, 214, as well as the bridge portion 216 are relatively stiff and not plastically deformable within the limits of force applied to the arms during use, while the retainer 222 is relatively easily plastically deformable by the clip applier.

Appellants stated on page 24, line 11 of the specification, that, referring now to Figures 2-4 and 17-18, when the clip 210 is pushed forward in the clip applier with the jaws 22, 24

of the clip applier closed, the retainer 222 is bent across the opening 230 between the first and second arms 212, 214 and into engagement with the end catch 220 of the first arm 212 as shown in Figure 18. The anvil formed by the grooves on the interior of the hooks 46, 48 of the clip applier jaws guide the bending of the retainer 222 causing it to puncture the fundus and couple to the end catch 220.

Appellants further state on page 24, line 20, that the clip 210 shown in Figures 17 and 18 is provided with an optional bendable barb 232 which provides a secondary stabilizing fixation point which helps keep the clip from rotating. As the clip is pushed forward over the fundus, tissue catches the barb 232 and bends it as shown in Figure 18.

It is described on page 25 of the specification, line 1, that the clip 210 is also provided with an ear 233 on the bridge 216. The ear is used by the pushing mechanism (not shown) to grasp the end of the clip when it is loaded into the clip applier.

It is also described in the last paragraph on page 25, that a second embodiment of a clip 310 according to the invention is shown in Figures 19 and 20. The clip 310 has two arms 312, 314 connected by a bridge 316. Both arms terminate in

retainers 320, 322, each having a sharp end 321, 323. The clip 310 is also provided with a pair of ears 333, 335 on the bridge 316. The ears are used by the pushing mechanism (not shown) to grasp the end of the clip when it is loaded into the clip applier. This embodiment is intended for use with a clip applier having hooks with interior grooves which diverge, or which are in parallel planes. With reference to Figures 2-4 and 15-16, when the clip 310 is pushed forward, the retainer 320 is bent by the groove inside the hook 46 and the retainer 322 is bent by the groove inside the hook 48 to the configuration shown in Figure 20. From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener. Thus, it will also be appreciated that the retainers 320, 322 are significantly longer than the retainer 222 shown in Figures 17 and 18 and preferably are of a length at least  $\pi$  times the distance between the arms 312, 314. Insofar as the retainers 320, 322 each form a complete fastener, the function of the arms 312, 314 and the bridge 316 may be considered redundant.

Appellants explained on page 26 of the specification, line 1, that Figures 21-23 illustrate a third embodiment of a clip 410 according to the invention. The clip 410 is similar to the clip 310 (with similar reference numerals increased by 100 referring to similar parts) except that the retainers 420, 422



are removable from the arms 412, 414. The arms 412, 414 terminate in female couplings 413, 415 which receive ends of the retainers 420, 422 in a slight interference fit. The clip 410 is also provided with a pair of ears 433, 435 on the bridge 416. The ears are used by the pushing mechanism (not shown) to grasp the end of the clip when it is loaded into the clip applier. The ears 433, 435 may also be used as a structure by which to engage a clip applied over tissue, e.g., with a snare, to pull and remove the clip from the tissue. The clip 410 is applied to the fundus in substantially the same way as described above with reference to the clip 310. However, after the retainers 420, 422 are bent by the anvils and the jaws are opened, the clip 410 is not released from the clip applier and the retainers are separated from the arms 412, 414. The resulting fastener formed by the retainers 420, 422 is shown in Figure 23. This is actually two substantially parallel "b" shaped fasteners. Thus, it may only be necessary to apply a single retainer as shown in Figure 24, for example.

Figures 24 and 25 illustrate a fourth embodiment of a clip 510. The clip 510 is similar to the clip 310 (with similar reference numerals increased by 200 referring to similar parts) with the addition of a central prong 540 extending between the arms 512, 514. The prong 540 preferably includes a set of irritators 542 as well as a barbed tip 544.

The prong 540 prevents undesirable movement of the clip 510 in a direction perpendicular to the axis of the prong when a clip is applied over tissue. The clip 410 is applied to the fundus in substantially the same way as described above with reference to the clip 310.

References Cited:

4,430,997	DiGiovanni et al.	Feb. 4, 1984
5,575,802	McQuilkin et al.	Nov. 19, 1996
2002/0104199 A1	Chen	Aug. 8, 2002

Grounds of Rejection to be Reviewed on Appeal

1. Whether or not claims 1, 2, 4, 5, 7, and 21-26 are anticipated by McQuilkin et al. (U.S. 5,575,802; hereinafter "McQuilkin") under 35 U.S.C. § 102(b).
2. Whether or not claims 17 and 18 are anticipated by DiGiovanni et al. (U.S. 4,430,997; hereinafter "DiGiovanni") under 35 U.S.C. § 102(b).
3. Whether or not claims 1, 3-6, 21-25, and 28 are anticipated by Chen (US 2002/0104199 A1; hereinafter "Chen") under 35 U.S.C. § 102(e)

Grouping of Claims:

Claims 1, 17, 21, and 22 are independent. Claims 2 to 10 depend on claim 1. Claim 18 depends on claim 17. Claims 23 to 31 depend on claim 22.

The patentability of claims 1, 2, 4, 5, 7, and 21-26 over McQuilkin are argued together for the sake of clarity and to eliminate redundancy of the arguments set forth herein. While claims 2 to 7 depend on claim 1, they disclose additional features not disclosed in the prior art and are argued separately. Accordingly, they do not stand or fall with claim 1. The Examiner has indicated that Claims 8 to 10 would be allowable if rewritten into independent form and therefore,

also do not stand or fall with claim 1. Claims 8 to 10 have not been rewritten, however, because Appellants believe that the present claims are not anticipated and they are allowable as written.

The patentability of claims 17 and 18 over DiGiovanni are argued together to eliminate redundancy of the arguments set forth herein and, therefore, claim 18 does not stand or fall with claim 17.

The patentability of claims 1, 3-6, 21-25, and 28 over Chen are argued together for the sake of clarity and to eliminate redundancy of the arguments set forth herein. While claims 23-26 and 28 depend on claim 22, they disclose additional features not disclosed in the prior art and are argued separately. Thus, they do not stand or fall with claim 22. The Examiner has indicated that claims 27 and 29-31 would be allowable if rewritten into independent form. Claims 27 and 29 to 31 have not been rewritten, however, for the same reasons set forth above.

Argument:

1. Claims 1, 2, 4, 5, 7, and 21-26 are not anticipated by McQuilkin.

In item 1 on page 2 of the above-identified Office action, claims 1, 2, 4, 5, 7, and 21-26 have been rejected as being anticipated by McQuilkin under 35 U.S.C. § 102(b). The Examiner has taken the position that the first hinge 16 of the McQuilkin sterilization clip anticipates the U-shaped bridge in Appellants' surgical clip. As discussed in detail below, however, the U-shaped feature disclosed by McQuilkin is not only structurally distinct from Appellants' device but is functionally different. Because the elements differ in both structure and function, the Honorable Board should overturn the Examiner's rejection and allow the referenced claims over 35 U.S.C. § 102(b)

Anticipation under 35 U.S.C. § 102(b) requires the presence in a single prior art reference each and every element of a claimed invention arranged as in the claimed invention. See e.g., Eolas Technologies, Inc. v. Microsoft Corp., 399 F.3d 1325, 1335 (Fed.Cir. 2005). Where the elements of a claimed invention are arranged differently or function differently, there is no anticipation. Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick, Co., 730 F.2d 1452, 1459 (Fed.Cir. 1984) (lower court erred finding anticipation when it treated

"the claims as mere catalogs of separate parts, in disregard of the part-to-part relationship, set forth in the claims and that give the claims their meaning"). To determine whether prior art anticipates an invention, one must identify the elements of the claimed invention, determine their meaning in light of the specifications and prosecution history and identify corresponding elements disclosed in the allegedly anticipatory reference. Id.; SSIH Equipment S.A. v. U.S.I.T.C. 718 F.2d 365, 377 (Fed. Cir. 1983) (in determining whether prior art anticipates an invention, court must determine what are the elements of a claim and what does the reference disclose). To anticipate a claimed invention, the elements disclosed in a prior art reference must function in substantially the same way to produce substantially the same result as in the claimed invention. Tate Eng'g v. U.S., 477 F.2d 1336, 1342 (Ct. Cl. 1973).

Examiner's rejection of the above claims, however, fails to appreciate the structural as well as functional differences between the U-shaped bridge disclosed by Appellants and the McQuilkin clip. Claim 1 calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending past one end of the arms in a direction, wherein the retainer has a length in the direction of at least  $\pi$  times the distance between the arms when the arms are substantially parallel.

Claim 21 calls for, *inter alia*, a surgical clip, including :

a bridge connecting the first and second arms to form a substantially U-shaped structure with the first and second arms being substantially parallel to one another; and

at least one deformable retainer extending past one end of the arms in a direction, the retainer having a length in the direction equal to a multiple of a distance between the arms, the multiple being greater than 2.5.

Claim 22 calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending from one of  
said arms and having a deformable portion, said  
deformable portion of said retainer having a length of at  
least approximately  $\pi$  times the distance between said  
arms when said arms are substantially parallel.

Simply put, claims 1, 21, and 22 provide that "a bridge connects said first and second arms to form a substantially U-shaped structure." By definition, a "U-shaped structure requires some positive distance between the two arms of the U-shape. If there is no distance, then it cannot be considered U-shaped. When the two jaws 12, 14 are parallel, McQuilkin has no separation distance therebetween. Therefore, the McQuilkin clip cannot be considered U-shaped and, accordingly, cannot anticipate 1, 21, or 22 because it does not disclose a structurally equivalent element. While McQuilkin is not U-shaped when the clip is functional, Appellants' device is.

To make up for the clear deficiency of McQuilkin, the Examiner proposes that the silicon rubber lining disclosed in 18, 20 is separate from the jaws 12, 14. McQuilkin provides no support for the Examiner's argument, however, and if it were true, it would render the McQuilkin clip ineffective for its intended purpose. McQuilkin recites features of the liner at:



Col. 1, lines 20 to 21, 37 to 38, 55 to 59;

Col. 2, lines 15-21, 52 to 67;

Col. 3, lines 1 to 4, 11, 40 to 41; and

Col. 4, lines 5 to 11, 20 and 39.

In each and every particular configuration, the McQuilkin liner 18, 20 is disclosed as being non-removably fixed to the upper and/or lower jaws 12, 14. Even though made of different material, it is never separate from the jaws 12, 14. A solitary disclosure of *how* the liner 18, 20 *contacts* the jaws 12, 14 is found at col. 2, lines 56 to 58 - "a suitable adhesive is used to fix the lining to the jaws 12, 14."

(Emphasis added by appellants.) Because the lining 18, 20 is always fixed to the jaws 12, 14, the combination of the lining and jaw 12, 14 and the 14, 20 function as a single *integral* part.

Indeed McQuilkin cannot achieve its intended clipping purpose - sterilization, as set forth in each and every one of its 10 claims - unless the distance between the jaws 12, 14, 18, 20 is equal to zero. Any positive distance between the jaws would not allow the clip to achieve its function of isolating and occluding the vessel(s) clamped between the jaws. McQuilkin uses the liner 18, 20 to absolutely ensure that there is *no separating distance between the jaws 12, 14* when

the jaws 12, 14 are in the closed position. Because the distance between:

the two surfaces of the liner 18, 20 (col 1, lines 37 to 38); or

one surface of the jaws 12 or 14 and one surface of the liner 18 or 20 (col. 2, lines 59 to 67),

always touch one another, the McQuilkin clip can never be considered as having a functional U-shaped structure as set forth and defined in the present application.

Thus, to function for its intended purpose, i.e. providing for "sexual sterilization", see e.g., Abstract, col. 1, lines 3 to 6, and each and every Claim 1 to 10, the McQuilkin clip requires direct and unseparated contact between the silicon rubber lining 18, 20 of the jaws 12, 14. FIG. 1 illustrates the clip in the open position prior to use. FIGS. 2 and 3 illustrate the clip in the closed and closed-fastened positions, respectively. The McQuilkin clip functions by clamping either the Fallopian tube or vas deferens in order to effect occlusion. To work, the silicon rubber lining 18, 20 of the jaws 12, 14 must be in direct contact. In other words the distance between jaws 12, 14 **must be zero**. Therefore, the McQuilkin retainer cannot equate to a retainer with a length of greater than 2.5 or  $\pi$  "times the distance between the arms

when the arms are substantially parallel" as set forth in claims 1, 21, and 22 (see also claim 17).

When in the non-applied (open) position, the McQuilkin jaws are not parallel. The only time they are parallel is when the clip is in the occluding (closed) position and the silicone rubber linings 18, 20 are in direct and unseparated contact. In order to function, therefore, McQuilkin does not and cannot teach two arms having a "distance between the arms when the arms are substantially parallel" to one another as set forth in claims 1, 17, 21 and 22.

The Examiner's rejection further ignores that the function of Appellants U-shaped bridge is very different from that served by the first hinge 16 in McQuilkin. In the present invention, the U-shaped bridge functions to gather and hold in place plicated tissue for clipping. McQuilkin does not act to plicate tissue, although it does act to occlude Fallopian tubes or vas deferens. Occlusion is not a function of the first hinge 16, but rather of the deformable, silicon, rubber lining 18, 20 integrally and fixedly attached to the jaws of McQuilkin's device. Thus, to the extent that McQuilkin gathers and holds tissue, it is not a function of any shape reflected in McQuilkin, as it is in the present invention, but rather of the material that McQuilkin employs.

With respect to the retainer of the present invention, the Examiner further ignores the language and features of the claims. Claims 1, 21 and 22 disclose a surgical clip with a retainer extending  $\pi$  times, greater than 2.5 times, or  $\pi$  times, the distance between the arms, with the arms substantially parallel to one another. Notwithstanding the Examiner's error in asserting that there is any functional distance between the arms of the McQuilkin clip, McQuilkin does not disclose a retainer extending " $\pi$  [or greater than 2.5] times the distance between the arms when the arms are substantially parallel". Even under the Examiner's mistaken construction, the McQuilkin retainer does not extend the distances set forth in the claims of the present invention. First, the McQuilkin retainer is curved and does not extend in the direction of the jaw. This leads the Examiner to mistake the outer circumference of the retainer, 140, for an extension past the arm in the direction of the extension. The actual distance of the extension, i.e., the extension of the retainer past the jaw is not specifically disclosed but, at a maximum, can be no greater than 4mm (the length L3) but, in function, extends far less because the distance between the hinge 144 and the tooth 150 in the direction is less than 2mm.

Furthermore, the feature in the present claims that the retainer extends in a direction allows the gathering of plicated tissue into the clip, as depicted for example in FIGS. 14 and 17. What the Examiner erroneously considers the "extension" of the retainer in McQuilkin does not function in the same way because of its curved shape. The McQuilkin clip is used to occlude a discrete vessel, Fallopian tubes, or vas deferens, so the curved retainer does not compromise its functionality. But the curved McQuilkin retainer would obstruct the gathering of plicated tissue in devices such as the present invention. For these reasons as well, Appellants believe claims 1, 21 and 22 are allowable over McQuilkin. Each discloses a retainer extending in a direction and having a greater length than that shown in McQuilkin.

Appellants' dependent claims also present different structural features not disclosed by McQuilkin, thereby also rendering Examiner's Section 102(b) rejection erroneous. As a result, the claims addressed below do not stand or fall with Claim 1. Claims 2 and 23 of the present invention disclose a surgical clip having a first arm and retainer of lesser thickness. McQuilkin discloses a clip having one arm and a retainer of equal or greater thickness. Examiner's rejection is based not on the thickness of the retainer portion but rather of the hinge which attaches the retainer to the lower jaw 14. Due to

the unitary plastic construction of the clip, the hinge is necessarily the thinnest section of the frame. When the structure the Examiner identifies as the retainer itself is measured (L4), it is apparent that the thickness is, at a minimum, equal to the jaw and significantly thicker elsewhere.

Claims 4 and 25 disclose a retainer wherein the retainer has a sharp tip. Although the Examiner contends that McQuilkin discloses a retainer with a sharp tip, simple reference to the features the Examiner recites dispels such a contention. While reference numerals 150 and 126 indicate teeth used for interlocking the McQuilkin clip, they are not shown or described as having a sharp tip. Thus, the Examiner is simply mistaken.

Similarly, the Examiner errs in arguing that McQuilkin discloses "decouplable" retainers like the present invention does in claims 5 and 26. He argues on page 3 of the Final Office Action that "if one were to disassemble hinge (16)" (emphasis added by appellants), the upper jaw of McQuilkin (12) would decouple from the retainer (140). First, there is no suggestion anywhere in McQuilkin that the first hinge 16 can be disassembled. Indeed, McQuilkin states that:

[i]t is a further object of the present invention to provide sterilization clips which may be manufactured with a frame comprising a single piece of plastics material. (Emphasis added by Appellants.)

McQuilkin would entirely lose its intended purpose if so disassembled! Further, given the interlocking tooth mechanism that McQuilkin describes to fasten the upper jaw 12 to the retainer 140, upon the non-suggested disassembly of the hinge 16, the jaw 12 would in fact detach from 140.

For the reasons set forth above, which are incorporated herein by reference, claims 7, 24, and 28 of Appellants device are not anticipated by McQuilkin. Those claims disclose a surgical clip comprising two arms each of which has an associated retainer of approximately the same length equipped with a sharp tip. McQuilkin does not disclose a retainer with a single associated arm and without a sharp tip.

For all of these reasons, claims 1, 21, and 22 are allowable and the rejection under Section 102(b) should be reversed. Claims 1, 21, and 22 are believed to be patentable over McQuilkin. The dependent claims 2, 4, 5, and 7 are believed to be patentable as well in addition to being ultimately dependent on claim 1. The dependent claims 23 to 26 are

believed to be patentable as well in addition to being ultimately dependent on claim 22.

2. Claims 17 and 18 are not anticipated by DiGiovanni

DiGiovanni discloses a multiple clip applier used to apply clips like those disclosed in McQuilkin. See, in particular, FIG. 2A of DiGiovanni. Therefore, all of the arguments above with respect to McQuilkin are equally applicable to distinguish DiGiovanni from the present invention and are hereby incorporated herein by reference. It is particularly noted that the DiGiovanni clips function and are set "to ligate a vessel", are set "about the vessel to be ligated", and/or are "set to ligate the vessel." See DiGiovanni at col. 1, line 15, col. 2 lines 5, 31, and 40 respectively. (emphasis added by Appellants). "Ligation" requires no distance between the arms of the clip ligating the vessel. Thus, when parallel, the DiGiovanni arms must have zero distance between them in order to effect ligation.

For all of these reasons, claims 17 and 18 are allowable and the rejection under §102(b) should be reversed. Claims 17 and 18 are, therefore, believed to be patentable over DiGiovanni.



3. Claims 1, 3 to 6, 21 to 25, and 28 are not anticipated by Chen

The Examiner rejected Claims 1, 3 to 6, 21 to 25, and 28 as fully anticipated by Chen. Chen discloses a paper clip formed from repeating rectangular coils of a continuous piece of metal wire. The Examiner's rejection of the present claims is based on his erroneous contention that no structure is given to the word "retainer" in claims 1, 21, or 22 of the present invention. The Examiner therefore argues, in essence, that Chen may be uncoiled to produce Appellants' clips and therefore Chen anticipates. Because Appellants believe that the present application recites sufficient structure, and for the other reasons discussed below, Chen does not anticipate the claims of the present invention.

Specifically, Claim 1 calls for, *inter alia*, a surgical clip, including:

at least one deformable retainer extending past one end of the arms in a direction, wherein the retainer has a length in the direction of at least  $\pi$  times the distance between the arms when the arms are substantially parallel.

Next, claim 21 calls for, *inter alia*, a surgical clip,  
including:

at least one deformable retainer extending past one end  
of said arms in a direction, said retainer having a  
length in said direction equal to a multiple of a  
distance between said arms, the multiple being greater  
than 2.5.

Finally, claim 22 calls for, *inter alia*, a surgical clip,  
including:

at least one deformable retainer extending from one of  
the arms and having a deformable portion, the deformable  
portion of the retainer having a length of at least  
approximately  $\pi$  times the distance between the arms when  
the arms are substantially parallel.

Each of these claims provide a structure of "at least one  
deformable retainer."

Chen neither discloses nor suggests the structure set forth in  
the present claims. Nowhere does Chen mention or suggest a  
deformable retainer extending "past one end of the arms" as  
set forth in claims 1 or 21. Nor does Chen disclose or

suggest a retainer having a deformable portion with a length  $\pi$  times the distance between the arms when the arms are substantially parallel as set forth in claims 1 or 22.

The Examiner errs in arguing that because the entirety of the Chen paper clip is deformable, the Examiner can compare the entire length of the paper clip to the retainer of claims 1, 21, and 22. This is tantamount to arguing:

because Chen's paper clip is made of a deformable wire, it could, therefore, be uncoiled and reshaped into another structure. Thus, Chen anticipates any possible structure into which the wire could be formed.

Such argument is specious at best. The claims of the present invention disclose a first and second arm as well as a bridge and reflect the structure discussed above. The retainer extends from one of the arms or past one end of the arms. Thus, the retainer of the present invention is not comparable to a portion of the Chen paper clip. Further, there is absolutely no suggestion in Chen to deform the paper clip in the way suggested by the Examiner. Indeed, to do as Examiner suggests and uncoil the Chen paper clip would defeat the primary object of Chen:

"to form a plurality of overlapping clipping portions",  
see Chen at paragraph [0005]; or

in order to allow for the clipping together of "different groups of documents" using the same clip, see Chen at paragraph [0004].

Chen discloses a paper clip made up of repeating, rectangular clipping portions formed from a continuous wire. If, as Examiner proposes, the clip is unwound, the Chen "retainer" would cease to function as it is supposed to function in Chen -- as an integral element connecting one clipping portion to the next.

As with the Examiner's construction of McQuilkin, the Examiner errs in rejecting claim 1 of the present invention over Chen. Chen does not disclose a retainer extending in a direction and having "a length in said direction of at least approximately  $\pi$  times the distance between the arms when the arms are substantially parallel." Emphasis added by Appellants. Chen's drawings, in fact, disclose a retainer having a length equal to (or slightly more when the retainer is curved as in FIG. 3) the distance between the arms -- not " $\pi$  times" greater. Indeed for Chen to function as a clip, the length of the retainer must equal or, at most, slightly exceed when curved, the distance between the clipping arms. For the same reasons, Chen does not anticipate claim 21 which recites a retainer having a slightly lesser extension -- 2.5.

Similarly, the Examiner's rejection of claim 22 should be overturned.

As with McQuilkin, the dependent claims rejected by Examiner include features not contained in Chen and, therefore, should be allowed over Section 102(b). Chen also fails to disclose a retainer having a sharp tip as do claims 3, 4, 24 and 25 of the present invention. While the Examiner contends that Chen discloses a sharp tipped retainer, he does not identify any disclosure or structure in Chen that reflects his contention. Again the Examiner simply appears mistaken. Nor does Chen disclose decouplable retainers as do claims 5 and 6 of Appellants' device. Claim 6 reflects the further feature that the retainer is coupled to an arm of the clip using a friction fit. The Examiner's response, that the "retainer *could be* wrapped around either or both arms and be maintained by friction" does not explain how Chen discloses decouplable retainers nor any suggestion of a mechanism in Chen allowing for a friction fit. Emphasis added by Appellants.

With respect to the present device, claims 23 and 28 disclose a retainer or retainers having lesser thickness than the associated arms. There is no similar disclosure in Chen where there is only disclosed a paper clip made from a wire having a uniform thickness.

Finally, Appellants note that the final rejection based upon Chen dated January 5, 2005 is verbatim, the same rejection set forth in the non-final rejection of June 23, 2004. After the non-final rejection, claims 1, 21, and 22 were amended but the final rejection made no mention of the amendments. It is, therefore, submitted that the failure of the Examiner to address the amendments constituted acquiescence to the correctness of Appellants' arguments.

For all of these reasons, claims 1, 21, and 22 are allowable and the rejection under §102(b) should be reversed. Claims 1, 21, and 22 are, therefore, believed to be patentable over McQuilkin. The dependent claims 4, 5, and 6 are believed to be patentable as well because they all are ultimately dependent on claim 1. Claims 23 to 25 and 28 are believed to be patentable as well because they all are ultimately dependent on claim 22. The dependent claims are believed to be patentable, however, without regard to whether claim 1 or 22 falls for the reasons identified above.

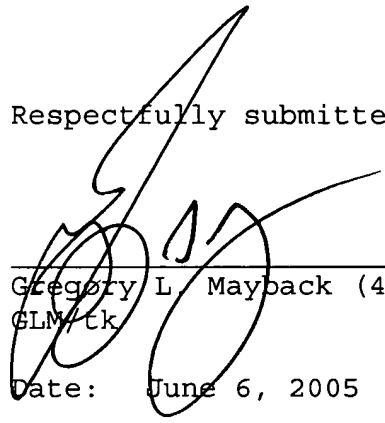
For the foregoing reasons, Appellants believe none of the prior art cited anticipates the present claims. Appellants therefore respectfully urge that this honorable Board reverse

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the final rejection of the Primary Examiner and to allow  
claims 1-10, 17, 18, and 21-31.

Please charge payment in the amount of \$500.00 to cover the  
fee for filing the *Brief on Appeal* to Deposit Account No.  
502524 in the name of Feldman Gale, P.A..

Respectfully submitted,

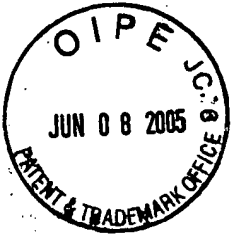


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Date: June 6, 2005

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Appendix - Appealed Claims:

1. A surgical clip, comprising:
  - a) a first arm;
  - b) a second arm;
  - c) a bridge connecting said first and second arms to form a substantially U-shaped structure;
  - d) at least one deformable retainer extending past one end of said arms in a direction, wherein said retainer has a length in said direction of at least approximately  $\pi$  times the distance between the arms when the arms are substantially parallel.
2. A surgical clip according to claim 1, wherein:

said first arm has a first thickness and said retainer has a second thickness smaller than said first thickness.
3. A surgical clip according to claim 1, wherein:

said at least one deformable retainer extending from one of said arms includes two deformable retainers, one extending from each of said arms, both retainers having a sharp tip and both retainers being approximately the same length.
4. A surgical clip according to claim 1, wherein:

said retainer has a sharp tip.



5. A surgical clip according to claim 1, wherein:

said retainer is decouplable from said one of said arms.

6. A surgical clip according to claim 5, wherein:

said retainer is removably coupled to said arms by a friction fit.

7. A surgical clip according to claim 2, wherein:

said at least one deformable retainer extending from one of said arms includes two deformable retainers, one extending from each of said arms, both retainers having a sharp tip and both retainers being approximately the same length.

8. A surgical clip according to claim 7, wherein:

said retainers are decouplable from said arms.

9. A surgical clip according to claim 8, wherein:

said retainers are removably coupled to said arms by friction fits.

10. A surgical clip according to claim 9, wherein:

each of said arms includes an end portion defining a slot, and each of said deformable retainers includes a proximal portion which has a friction fit with a respective slot.

11 to 16 (canceled).

17. A kit, comprising:

- a) at least one surgical clip; and
- b) an applier for applying said at least one surgical clip to tissue, wherein

said at least one surgical clip comprises a first arm, a second arm, a bridge connecting said first and second arms to form a substantially U-shaped structure, and at least one deformable retainer extending from one of said arms, wherein said retainer has a length of at least approximately  $\pi$  times the distance between the arms when the arms are substantially parallel.

18. A kit according to claim 17, wherein:

said at least one surgical clip comprises a plurality of surgical clips.

19 to 20 (canceled).

21. A surgical clip, comprising:

a first arm;

a second arm;

a bridge connecting said first and second arms to form a substantially U-shaped structure with said first and second arms being substantially parallel to one another;

at least one deformable retainer extending past one end of said arms in a direction, said retainer having a length in said direction equal to a multiple of a distance between said arms, said multiple being greater than 2.5.

22. A surgical clip, comprising:

a first arm;

a second arm;

a bridge connecting said first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending from one of said arms and having a deformable portion, said deformable portion of said retainer having a length of at least approximately  $\Pi$  times the distance between said arms when said arms are substantially parallel.

23. A surgical clip according to claim 22, wherein said first arm has a first thickness and said retainer has a second thickness smaller than said first thickness.

24. A surgical clip according to claim 22, wherein said retainer extending from one of said arms includes two deformable retainers, one extending from each of said arms, both retainers having a sharp tip and both retainers being approximately the same length.

25. A surgical clip according to claim 22, wherein said retainer has a sharp tip.

26. A surgical clip according to claim 22, wherein said retainer is decouplable from said one of said arms.

27. A surgical clip according to 26, wherein said retainer is removably coupled to said arms by a friction fit.

28. A surgical clip according to claim 23, wherein said deformable retainer extending from one of said arms includes two deformable retainers, one extending from each of said arms, both retainers having a sharp tip and both retainers being approximately the same length.

29. A surgical clip according to claim 28, wherein said retainers are decouplable from said arms.

30. A surgical clip according to claim 29, wherein said retainers are removably coupled to said arms by friction fits.

31. A surgical clip according to claim 30, wherein each of said arms includes an end portion defining a slot, and each of said deformable retainers includes a proximal portion having a friction fit with respective slot.